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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,530	11/13/2003	Andrew Thomas Forsberg	47563.0014	9304

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HOLLAND & HART LLP
60 E. South Temple, Suite 2000
P.O. Box 11583
Salt Lake City, UT 84110

EXAMINER	
COLELLO, ERIN L	
ART UNIT	**PAPER NUMBER**
3734	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,530	FORSBERG ET AL.	
	Examiner	Art Unit	
	ERIN COLELLO	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,13-16,20,21,28,45-49,51-54 and 57-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13-16,20,21,28,45-49,51-54 and 57-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed January 14, 2009. Claims 50, 55 and 56 have been canceled without prejudice. Claims 1, 13-16, 20-21, 28, 45-49, 51-54 and 57-60 are pending and an action on the merits is as follows.

Applicant's arguments with respect to claims 1, 13-16, 20-21, 28, 45-49, 51-54 and 57-60 have been considered but are moot in view of the new ground of rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 13-16, 20-21, 28, 45-49, 51-54 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ginn et al. (US 6,626,918 B1).**

Regarding claims 1, 13, 20, 28, 45-48 and 52-54, Ginn discloses a vascular insertion assembly, comprising: an insertion sheath having a distal end and a proximate end (Figure 10, (212)); a dilator having a distal end and a proximate end, sized to fit inside the insertion sheath (Figure 10, (214)), the dilator having a distal end positionable distally beyond a distal end of the insertion sheath (Figure 11, (232)); a first distal hole (first inlet port referred to from herein out as first distal hole) located in the distal end of the dilator (Figure 10, (249)); a first indicator (first proximal hole/ first outlet port/ first drip hole all referred to from herein out as first indicator) located at a proximal end of the

dilator (Figures 10 and 11, (247)), the first indicator being in fluid communication with the first distal hole so that when the first distal hole penetrates a vessel the first indicator indicates an initial penetration of the vascular insertion assembly into the vessel (Column 6, Lines 19-35; Column 7, Lines 7-18; Column 9, Lines 1-15; Column 10, Lines 41-52); a second distal hole (second inlet port/over insertion hole referred to from herein out as second distal hole) located in the distal end of the insertion sheath, wherein the second distal hole and the first distal hole are spaced apart from each other in a lengthwise direction of the vascular insertion assembly (Figure 10, (250)); and a second indicator (second proximal hole/ second outlet port/over insertion indicator/second drip hole all referred to from herein out as second indicator) located at a proximal end of the insertion assembly (Figure 10, (251)), the second indicator being in fluid communication with the second distal hole so that when the second distal hole penetrates the vessel the second indicator indicates over insertion of the vascular insertion assembly into the vessel (Figure 16A-B, (544)) wherein the vascular insertion assembly is configured so that the first distal hole provides an indication that the vascular insertion assembly has penetrated a vessel at one depth and the second distal hole provides an indication that the vascular insertion assembly has penetrated another depth in the vessel that is too far into the vessel; wherein the vascular insertion assembly is configured so that fluid flows out of the first indicator when the first distal hole enters a vessel and fluid flows out of the second indicator when the second distal hole enters the vessel (Column 6, Lines 19-35; Column 7, Lines 7-18; Column 9, Lines 1-15; Column 10, Lines 41-52).

Ginn fails to explicitly disclose that the first distal hole is located on the portion of the dilator that extends beyond the insertion sheath.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the first distal hole so that it was on the portion of the dilator that extends beyond the insertion sheath, since it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

Ginn fails to explicitly disclose that the second indicator is at the proximal end of the insertion sheath.

However, in an alternative embodiment, Ginn teaches that it is well known in the art for the second indicator pass through the proximal end of the insertion sheath (Figure 16A-B, (550), (648), (544)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the second indicator and the second lumen to pass through the insertion sheath as taught by Figures 16A-B of Ginn, since such a modification makes it easier to distinguish between the two visual indicators.

Regarding claim 14, Ginn discloses that a first lumen provides the fluid communication between the first distal hole and the first indicator; wherein the first lumen passes through the dilator (Figure 11, (249), (248), (247)).

Regarding claim 15, Ginn discloses that a second lumen provides the fluid communication between the second distal hole and the second indicator; wherein the second lumen passes through the dilator (Figure 11, (250), (252), (252)).

Regarding claim 16, Ginn discloses that a second lumen provides the fluid communication between the second distal hole and the second indicator but fails to explicitly disclose that the second indicator and the second lumen pass through the insertion sheath.

However, in an alternative embodiment, Ginn teaches that it is well known in the art for the second indicator and the second lumen to pass through the insertion sheath (Figure 16A-B, (550), (648), (544)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the second indicator and the second lumen to pass through the insertion sheath as taught by Figures 16A-B of Ginn, since such a modification makes it easier to distinguish between the two visual indicators .

Regarding claim 21, Ginn discloses a lumen having a first flow path (Figure 11, (248)) and a second flow path (Figure 11, (252)); wherein the first flow path provides the fluid communication between the first distal hole and the first indicator; and the second flow path provides the fluid communication between the second distal hole and the second indicator (Figure 11, (242), (250), (247), (251); Figures 16A-B, (544), (548)).

Regarding claim 49, Ginn discloses that the indication provided by the first distal hole and the second distal hole is at a proximal end of the vascular insertion assembly (Figure 11, (247), (251)).

Regarding claim 51, Ginn discloses all of the claimed limitations above including that there can be a number of side ports at different axial positions in order to provide a

visual indication that the assembly is at a plurality of known locations or depths but fails to explicitly disclose a third distal hole, third indicator and third lumen.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a plurality of distal holes, indicators and lumens passing through the vascular insertion assembly, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v Bemis Co.*, 193 USPQ 8.

Regarding claims 57-59, Ginn discloses that the first distal hole and the first indicator are in fluid communication by way of a lumen that passes through the dilator and the second distal hole and the second indicator are in fluid communication (Figures 10 and 11, (242), (250), (247)).

Ginn fails to explicitly disclose that the second distal hole and the second indicator are in fluid communication by way of a lumen that passes through the insertion sheath.

However, in an alternative embodiment, Ginn teaches that it is well known in the art for the second indicator and the second lumen that connects the second distal hole and the second indicator to pass through the insertion sheath (Figure 16A-B, (550), (648), (544)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the second indicator and the second lumen to pass through the insertion sheath as taught by Figures 16A-B of Ginn, since such a modification makes it easier to distinguish between the two visual indicators.

Regarding claim 60, Ginn discloses all of the claimed limitations above but fails to explicitly disclose that the first distal hole and the first indicator are in fluid communication by way of a lumen that passes through the insertion sheath and the second distal hole and the second indicator are in fluid communication by way of a lumen that passes through the insertion sheath.

However, in an alternative embodiment, Ginn teaches that it is well known in the art for an indicator and a lumen to pass through the insertion sheath (Figure 16A-B, (550), (648), (544)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the second indicator and the second lumen to pass through the insertion sheath as taught by Figures 16A-B of Ginn, since such a modification makes it easier to distinguish between the two visual indicators.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include two indicators and two lumens passing through the insertion sheath, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v Bemis Co.*, 193 USPQ 8.

Response to Arguments

1. Applicant's arguments with respect to claims 1, 13-16, 20-21, 28, 45-49, 51-54 and 57-60 have been considered but are moot in view of the new ground(s) of rejection.

- Applicant argues that there is no dilator in Ginn, since the sheath is positioned in the blood vessel without the use of a dilator or even an obturator and that the obturator of Ginn is placed within the sheath after the sheath is positioned.

However, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the sheath is positioned with the use of "a dilator" and that the obturator is placed within the sheath after the sheath is positioned) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Using the broadest reasonable interpretation, the word "dilator" means an instrument for enlarging a cavity, blood vessel or opening. The obturator of Ginn is moved back and forth within the blood vessel and is capable of being used to enlarge a cavity. Furthermore, the claim limitation only requires the dilator to be insertable within the sheath, which the obturator of Ginn clearly is and therefore, the arguments are not persuasive.

- Applicant argues that Ginn fails to disclose a first side port in fluid communication with a first indicator at the proximal end of the dilator and a second side portion in fluid communication with a second indicator located at a proximal end of the insertion sheath.

The Examiner respectfully disagrees. As shown above in the rejection, Ginn does in fact disclose a first side port in fluid communication with a first indicator at

the proximal end of the dilator (Figures 10 and 11, (242), (248), (247)) and a second side portion in fluid communication with a second indicator located at a proximal end of the insertion assembly (Figures 10 and 11, (250), (252), (251)). In that specific embodiment Ginn doesn't explicitly disclose that the second indicator can be within the insertion sheath, however, in an alternative embodiment, Ginn teaches that it is well known to have a second indicator on the insertion sheath (Figures 16A-B, (544)). And therefore it would have been obvious to make the second indicator to be within the insertion sheath as taught by Figures 16A-B of Ginn and for that reason the arguments are not persuasive.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN COLELLO whose telephone number is (571)270-3212. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734

EC
Art Unit 3734